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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,356	11/25/2003	Antonio Cutando Soriano	285.1001US	4724
7590 DAVIDSON, DAVIDSON & KAPPEL, LLC 14th Floor 485 Seventh Avenue New York, NY 10018			EXAMINER MAEWALL, SNIGDHA	
			ART UNIT 1612	PAPER NUMBER
			MAIL DATE 05/29/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,356	SORIANO ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 January 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-8, 13 and 14 is/are pending in the application.

4a) Of the above claim(s) 9-12 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-8 and 13-14 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) Notice of Informal Patent Application

6) Other: _____.

DETAILED ACTION

Summary

1. Receipt of applicants arguments/Remarks, amended claims and RCE filed on 01/22/08 is acknowledged.

Receipt of certified copy of Foreign priority Application filed on 01/22/08 is acknowledged.

Claims 1, 7 and 8 have been amended and new claims 13-14 have been added. Claims 9-12 have been withdrawn by Applicants.

Claims **1-8 and 13-14** are under prosecution.

The rejections made in the office action dated 07/16/08 have been withdrawn in view of Applicants amendments to the claims.

The following are new rejections.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "essential oil". The metes and bounds of the claim is not

defined. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-8 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Cutler (USP 5,900,230).

Cutler discloses dental product for the treatment of periodontal diseases (see abstract). The dental product is in the form of dentifrice pastes or gels, powders, granules (see abstract). The reference discloses melatonin from (0.1% to 1%) and antioxidant (claimed as active-autoxidant) such as ascorbic acid and coenzyme Q10. preservative such as paraben (see claim 17. Ethylcellulose (reads on hydrophobic excipient as claimed) and hydrophilic excipients such as polysaccharides are disclosed in claim 10 and 11. Essential oils are disclosed in claim 1. It should be noted regarding claim 14 that the products composition is disclosed in prior art and product being used in the form of animal feed is an intended use of the product/composition, as such bears no patentable weight.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-8 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neigut (USP 6,048,886).

Neigut discloses compositions and methods for the application of those compositions in order to treat biological surfaces, especially the skin (abstract). The composition disclosed contains antioxidants such as melatonin (abstract). Melatonin may be present at weight percentages ranging from 0.1% to 99% (see column 5, lines 25-30). The antioxidant greatly reduces the damage to skin and also improves the immunocompetance of the cells (see column 2, lines 15-35). Alcohol and oils are disclosed on column 5, lines 30-35). The reference teaches preparation with a carrier in examples and discloses that if desired, the formulation can be produced as an ointments, sprays, gels, suspensions, creams, powders or emulsions by adding emulsifiers, thickeners and surfactants during the manufacturing process (see column 9, lines 60-66).

Since the reference teaches the antioxidant and immunostimulating activity of melatonin and suggests that the formulation can be prepared, it would have been obvious to the

one of ordinary skilled in the art at the time of the instant invention to prepare an oral hygiene product such as tooth paste or animal feed or mouthwash with a reasonable expectation of success.

8. Claims 1-8 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neigut (USP 6,048,886) in view of US Cutler (USP 5,900,230) or vice versa.

Neigut discloses compositions and methods for the application of those compositions in order to treat biological surfaces, especially the skin (abstract). The composition disclosed contains antioxidants such as melatonin (abstract). Melatonin may be present at weight percentages ranging from 0.1% to 99% (see column 5, lines 25-30). The antioxidant greatly reduces the damage to skin and also improves the immunocompetance of the cells (see column 2, lines 15-35). The reference teaches preparation with a carrier in examples and discloses that if desired, the formulation can be produced as an ointment or emulsions by adding emulsifiers, thickeners and surfactants during the manufacturing process (see column 9, lines 60-66).

Neigut does not specifically teach preservatives or hydrophobic and hydrophilic excipients. Cutler discloses dental product for the treatment of periodontal diseases (see abstract). The dental product is in the form of dentifrice pastes or gels, powders, granules (see abstract). The reference discloses melatonin from (0.1% to 1%) and antioxidant (claimed as active-autoxidant) such as ascorbic acid and coenzyme Q10. preservative such as paraben (see claim 17. Ethylcellulose (reads on hydrophobic

excipient as claimed) and hydrophilic excipients such as polysaccharides are disclosed in claim 10 and 11.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate preservative and hydrophilic/hydrophobic excipients as taught by Cutler et al. because Cutler is directed towards dental product such as pastes and gels and Neigut suggests use of the disclosed formulation for oral, mouth surfaces which would benefit from the application of such preparations. Since Neigut discloses that melatonin acts as antioxidant and immunostimulant, it would have been obvious to the one of ordinary skilled in the art to prepare an oral hygiene product with antioxidant and immunostimulating activity for human and animal with a reasonable expectation of success.

9. Claims 1-8 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masterson USP 6,200,550) in view of US Cutler (USP 5,900,230) or Neigut (USP 6,048,886).

Masterson discloses toothpastes comprising 0.2 to 2 percent by weight of melatonin (column 7, line 2). The compositions contain conventional hydrophobic and hydrophilic excipients and also contain preservatives (column 8, line 51), with sorbic acid being used in working example 4 (column 12).

The reference does not disclose antioxidants. Cutler discloses dental product for the treatment of periodontal diseases (see abstract).The dental product is in the form of

dentifrice pastes or gels, powders, granules (see abstract). The reference discloses melatonin from (0.1% to 1%) and antioxidant (claimed as active-autoxidant) such as ascorbic acid and coenzyme Q10. Preservatives such as paraben are disclosed (see claim 17). Ethylcellulose (reads on hydrophobic excipient as claimed) and hydrophilic excipients such as polysaccharides are disclosed in claims 10 and 11. Essential oils are disclosed in claim 1. It should be noted regarding claim 14 that the products composition is disclosed in prior art and product being used in the form of animal feed is an intended use of the product/composition, as such bears no patentable weight. Neuget teaches antioxidant such as COQ_{sub}.10 along with vitamin A, B and C and further teaches that melatonin stimulates natural antioxidants and improve DNA repair and enhances the immune system. It would have been obvious to one of ordinary skilled in the art at the time the instant invention was made to incorporate ascorbic acid in the composition forwarded by Masterson et al. because antioxidants reduce the oxidative damage to the skin. A skilled artisan would thus have been motivated to combine the antioxidants to the Masterson composition and arrived at the claimed invention with the reasonable expectation of success.

Response to Arguments

10. Applicant's arguments with respect to claims 1-8 and 13-14 have been considered but are moot in view of the new ground(s) of rejection.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-

272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/
Examiner, Art Unit 1612

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612